

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:) Confirmation: 1770
Roy A. Ostgaard, et al.)
Serial No.: 09/156,952) Group Art Unit: 1743
Filed: September 18, 1998)
For: SAMPLE VIAL FOR USE IN) Examiner: Dwayne K. Handy
PREPARING CYTOLOGICAL)
SPECIMEN)

REPLY BRIEF-CFR 41.43

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Brief is in reply to the Examiner's Answer dated May 23, 2006. Appellant agrees with the statements made in item numbers (1)-(6), (8), and (11) of the Examiner's Answer. Appellant disagrees with the statements made in item numbers (9) and (10), and responds as follows.

Appellant agrees with the Examiner that claim 1 is drawn to a lug having a lower most surface that extends radially outward from the body outer surface along a PLANE perpendicular to said body outer surface," and that a "plane is a different geometric entity than a line." (See page 7, lines 9-12 of Examiner's Answer, page 7). However, in stark contrast to what the Examiner believes, Appellant is not "arguing that the line formed by the lowermost surface of the lug of the device must be perpendicular to the

body surface." (See page 7, lines 14-16 of Examiner's Answer). Appellant is arguing that the plane along which the lowermost surface of the lug of the device extends must be perpendicular to the body surface, as clearly recited in claim 1.

Part of the confusion appears to stem from the fact that Appellant has annotated Figure 5 of the application with a line representing a plane P1, and that the Examiner therefore believed that Appellant was arguing that the line representing plane P1, as opposed to the actual plane P1, must be perpendicular to the body surface. Notably, because Figure 5 is a two-dimensional side view of the device, only a line can accurately represent the claimed plane in this view. Indeed, Plane PL1 of Fig. B accompanying the Examiner's Answer is represented by a line; however, this does not make Plane PL1 any more of a plane than plane P1 illustrated in the annotated figure provided by Appellant.

While no other view of the plane P1 need be provided, since the plane P1 can easily be ascertained by visualizing a top view of the Figure 5 device, Appellant has attached herewith a copy of Figure. 4, which illustrates a top view of the exemplary embodiment of the claimed invention, and which has been annotated with plane P1. As can be see, the plane P1 is illustrated in two dimensions, thereby showing that plane P1 is truly a plane, and not a line. Thus, Appellant's arguments are indeed consistent with the claim language.

Based on the misconception that Appellant was arguing that the lines representing the planes P1-P3 (instead of the claimed planes P1-P3 themselves) should be perpendicular to the outer body surface, the Examiner stated that "the

pertinent issue for this argument is not what angle the line made by the lowermost surface of the lug forms with the body outer surface," but instead, "the issue is the angle formed between the plane that this line resides in and the body outer surface . . ." (See page 9, lines 2-6 of the Examiner's Answer). However, as made clear by the claims themselves and the corresponding arguments of Appellant, the pertinent issue relates to the angle formed between the plane along which the lowermost surface extends (i.e., plane P1) and the body outer surface—not the angle formed between the plane in which a line extension of lowermost surface extends and the body outer surface. There is nothing in the claims that defines the orientation of a line relative to the outer body surface, and Appellant never argues such.

The Examiner has annotated the Figure previously provided by Appellant (Figure A in the Examiner's Answer) with a Plane PL1 (represented by the dotted lines) that contains what the Examiner has called as line P3, and concluded that the lower-most surface of the Brodner device extends along a line that is contained in Plane PL1. (See page 9, lines 8-18 of the Examiner's Answer). The Examiner also annotated the Brodner figure with Plane PL1, and concluded that Plane PL1 is perpendicular to the outer body surface. (See page 9, lines 18 to page 10, line 3 of the Examiner's Answer).

Appellant does not disagree that the so-called line P3 resides within Plane PL1, as defined by the Examiner, and that Plane PL1 is perpendicular to the outer body surface. However, this is irrelevant to the determination of whether the lowermost surface of the Brodner lug extends along a plane that is perpendicular to the outer body surface (i.e., plane P2 illustrated by the dashed line in the annotated Brodner figure

provided by Appellant), as required by the claims and as argued by the Appellant. The actual plane that the lower-most surface of the Brodner lug extends (i.e., plane P3 illustrated by the dashed line in the annotated Brodner figure provided by Appellant) is simply not perpendicular to the outer body surface.

Thus, Appellant respectfully disagrees with the Examiner's original reasoning for sustaining the rejection of claims 1-8, 10, and 12-26 as being obvious in view of the combination of Brodner and Moore.

The Examiner has provided a further basis for sustaining the rejection of claims 1-8, 10, and 12-26. (See page 5, lines 16 to page 6, line 20 and page 10, line 9 to page 11, line 8 of the Examiner's Answer). Appellant responds to this new ground of rejection, as follows.

In concluding that Appellant's argument that the non-tapering lowermost surface of the lug of the claimed device is distinguishable over the tapering lowermost surface of the lug of the Brodner device is not persuasive, the Examiner states that the "anti-rotation element of Brodner serves the same function as applicant's lug even with the taper." (See page 10, lines 9-17 of the Examiner's Answer). Appellant fails to appreciate why the functionality the anti-rotation elements of the claimed invention and the ridges of the Brodner device are relevant to the determination of whether the claims are patentable over the prior art. That is, the fact that the elements of the claimed invention and Brodner function to prevent rotation of the vial body does not mean that the claimed invention cannot be patentable over Brodner. The patentability of the claims do not hinge on the function of the anti-rotation element, and Appellant is not

arguing that the claims are patentable over the Brodner device because the anti-rotation lugs of the claimed invention have a different function than do the ridges of the Brodner device.

As Appellant has consistently maintained, the claimed invention is patentable over the cited prior art based on the geometry and orientation of the anti-rotation elements. For example, requiring that each anti-rotation lug 18 have a lowermost surface that extends along a plane perpendicular to the outer surface of the body 12 ensures that the vial 10 will not (1) penetrate too deeply into the bores 52, 62, thereby causing the vial 10 to jam in the apparatus and frustrate the operation of the automated test apparatus; and (2) axially translate to an improper position when in the vial sleeve 64. (See Amendment and Response, dated October 19, 2001, page 8, line1 to page 9, line 7). In contrast, each of the ridges 56 of the Brodner device has a lowermost surface that extends along a plane that is oblique to the outer surface of the vial 10, which is a critical feature that allows the Brodner device to function correctly, as will be described in further detail below.

The Examiner essentially concludes that "Appellant's own disclosure and Appellant's lack of any evidence as to how this specific configuration or shape distinguishes Appellant's lug over the element from Brodner and Appellant" renders the claimed invention obvious. (See page 6, lines 7-21 of the Examiner's Answer). In support of this conclusion, the Examiner states that the specification provides that "other suitable materials, dimensions, and configurations for the body, the cap, the ribs, the lugs, the fluid level indicia and other features of the sample vial will be apparent to

those skill in the art, those disclosed being provided as examples only," and further states that the specification lacks textual support for the specific shape of the lowermost surface of the lug.

With respect to the broadening language in the specification, certainly, a trivial change in material (e.g., type of plastic), a trivial change in dimensions (e.g., having body 4 mm in length instead of 5 mm in length), ribs (having 7 ribs instead of 6 ribs), lugs (having 7 lugs instead of 6 lugs), would probably be obvious. However, Appellant fails to understand how this statement would render any and all possible modifications to the exemplary device obvious. Indeed, Appellant cannot find, and the Examiner has not cited a single case, where a broadening statement made in a specification rendered any and all changes to an exemplary embodiment obvious. In any event, the focus of the inquiry should be on whether there is any suggestion or motivation to modify the prior art device of Brodner—not the exemplary embodiment of the application. Appellant fails to understand why the broadening statement made in the application suggests that the Brodner device should somehow be modified—especially in the manner suggested by the Examiner. As the Examiner and this Board surely knows, the vast majority of issued patents have boilerplate language in their specifications stating that it would be obvious to those skilled in the art that various changes and modifications may be made to the preferred embodiments. However, such statements have evidently been held irrelevant to the determination of whether the claimed invention is patentable—as should the statement in the present application.

With respect to the lack of textual support for the claimed shape/orientation of the lowermost surface of the lug, Appellant is unaware of any case law that supports that proposition that there must be textual support or explicitly stated advantages of a claimed feature for a claim to be patentable. In fact, the Federal Circuit has held, and the PTO has restated, that a claimed feature is supported by the specification if it is illustrated in the figures or otherwise inherently disclosed in the specification, and has further held that advantages of the claimed feature need not be explicitly set forth in the specification (See M.P.E.P. §2163.07(a)). Thus, the lack of textual support for the orientation of the lowermost surface of the lug and its attendant advantages are irrelevant to the patentability of the claims over the prior art. That is, once a claimed feature is found to be supported by the specification, the Examiner must then fairly measure that feature against the prior art without further regard as to whether such feature is supported textually or by other means. The lack of any claim support perceived by the Examiner simply cannot be used as a basis for rejecting claims over prior art.

What is relevant to the patentability of claims in this case is whether there is any suggestion or motivation in the prior art to modify the lower-most surface of a ridge of the Brodner device in a manner that would make the claims obvious. (See M.P.E.P. §2143). Thus, instead of giving credence to matters that are irrelevant to the determination of whether the claims are obvious over the prior art, Appellant implores this Board to strictly follow the rule of law provided by the Federal Circuit and set out in the MPEP.

As previously stated throughout the prosecution of this application, no suggestion or motivation exists for modifying the Brodner device in the manner suggested by the Examiner. In particular, if the lowermost edges of the ridges 56 of the Brodner device were made to be perpendicular to the outer surface of the sleeve structure 12, the objective of Brodner would be defeated. It is an established principle that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there could be no suggestion or motivation to make the proposed modification. See In re Gordon, 733 F.2d 900 (Fed. Cir. 1984). Brodner indicates that the purpose of the ridges 56 is to provide a locking engagement with the ridges 68 of the tray 16 when the combination of the sleeve structure 12 and vial 10 is slid into the aperture 62 of the tray 16. Brodner specifically states:

The ridges 56 provide locking engagement of the combination 14 when the combination 14 is inserted into a receiving aperture 62 of the tray 16. Upper edges 64 extending about an opening 66 of the aperture 62 preferably contain a plurality of small ridges 68 which produce a locking type action when the ridges 56 are in pressing engagement thereagainst or between. (col. 3, lines 34-41).

It is clear, however, that if the lowermost edges of the ridges 56 were perpendicular to the outer surface of the sleeve structure 12, they would most likely abut against the uppermost edges of the tray ridges 68 when attempting to slide the sleeve structure 12 within the tray aperture 16. As a result, the sleeve structure 56 could not be mounted within the tray 16, or at the least, there would be difficulty in doing so without manual intervention by the user. Thus, the lowermost edges of sleeve structure ridges 56 must be tapered or beveled for the Brodner device to properly operate, and there would be no suggestion or motivation to modify them.

Appellant has attached Figures A1, A2, A3, B1, and B2. Figure A1 illustrates the tapered ridges of a vial body and tray much like those of the Brodner assembly. As can be best seen in Figure A2, when the tapered lowermost surface of a ridge of the vial body contacts the tapered uppermost surface of a ridge of the tray aperture, a bearing surface is created between the respective ridges. As a result, the respective ridges of the vial body and tray aperture will tend to slide relative to each other, as illustrated in Figure A3, thereby allowing the vial body to continue to slide within the tray aperture.

In contrast, Figure B1 the non-tapered ridges of a vial body and tray much like those of the Brodner assembly, as modified in accordance with the suggestions of the Examiner. As can be best seen in Figure B2, when the lowermost surface of a ridge of the vial body contacts the uppermost surface of a ridge of the tray aperture, no bearing surface is created between the respective ridges. As a result, the ridges cannot slide relative to each other. Notably, even if the uppermost surfaces of the tray aperture ridges remain tapered, as illustrated in Figure A1, while the lowermost surfaces of the vial body ridges remained non-tapered, as illustrated in Figure B3, there would still be difficulty in sliding the vial body within the tray aperture.

Thus, it is clear from the attached Figures that one of ordinary skill in the art would not be motivated to modify the Brodner device in the manner suggested in the art. It is also worth noting that Appellant has merely described herein simple geometric and physical principles that requires no intrinsic or extrinsic evidence to prove, and thus, does not constitute mere attorney argument or conjecture. In contrast to the Examiner's conclusory assertion that one of ordinary skill in the art would be motivated

to make the lowermost surfaces of the Brodner device ridges non-tapered, Appellant believes that it has provided more than a sufficient showing as to why one of ordinary skill in the art would not be so motivated.

To the extent that this Board relies on the previous Board's decision (see Decision of the Board of Patent Appeals and Interferences, dated October 22, 2003 ("Appeal Decision")) to hold that one of ordinary skill in the art would be motivated to modify the Brodner device in the manner suggested by the Examiner, Appellant comments as follows.

In the Appeal Decision, the Board stated:

Brodner does not disclose that the lower edges of the ridges are beveled or tapered, or indicate that they should be beveled or tapered, and the ridges in figure 4, particularly the one on the left side, appear to have lower edges which are perpendicular to the body outer surface. Thus, the ridges which Brodner would have been fairly suggested to one of ordinary skill in the art include ridges having lower edges which are substantially perpendicular to the body outer surface. (Appeal Decision, page 5, lines 7-15).

The Appeal Board seemed to have suggested from this excerpt that the fact that Brodner does not state that the lower edges of the ridges must be beveled or tapered suggests to one of ordinary skill in the art that the lowermost edges of the ridges can be perpendicular. It is true that Brodner does not explicitly forbid providing the ridges with perpendicular lower edges. This, however, is not tantamount to providing a suggestion that the lower edges can be modified to be made perpendicular to the outer surface of the body. Such suggestion is clearly absent in Brodner, especially in view of the fact that this modification would degrade the Brodner device, as discussed above. As for the ridges illustrated on the left side of Fig. 4, they are clearly shown as being tapered—

not perpendicular—to the outer surface of the body.

The Appeal Board further stated:

Brodner's sleeve outer ridges, however, do not need to press against the tray ridges but, rather, can slide between the tray ridges. Sleeve outer ridge lower edges which are perpendicular to the body outer surface would not interfere with the sliding of the outer sleeve ridges between the tray ridges. (Appeal Decision, page 5, line 20 to page 6, line 10).

Applicants agree that once the longitudinally disposed surfaces of the sleeve outer ridges and the tray ridges are actually engaged, the lower edges of the sleeve ridges will not interfere with the sliding of the outer sleeve ridges between the tray ridges. The problem arising from making the lowermost edges of the ridges perpendicular, however, does not occur when the ridges of the respective sleeve and tray have already engaged each other, but rather prior to. That is, in order to initially engage the ridges, the lower most edges of the sleeve ridges must be able to pass the uppermost edges of the tray ridges. As explained above, the use of ridges with lowermost edges that are perpendicular, as opposed to tapered or beveled, would make this difficult.

The Appeal Board indicated in footnote 1 of the Appeal Decision that:

Some rotation of the sleeve may be needed for the sleeve ridges to be positioned between the tray ridges, but such rotation also would be needed if the edges of the ridges were beveled.

Although, conceptually, the sleeve might be manually and deliberately rotated to prevent abutment between the lowermost edges of the sleeve ridges and the uppermost edges of the tray ridges, in practice, this would be very difficult to do due to the tightly toleranced ridges (as clearly illustrated in the figures of Brodner) required to

facilitate the locking action. That is, rotation of the sleeve relative to the corresponding tray aperture would have to be perfect to allow the sleeve ridges to slide within the equally dimensioned spaces between the ridges of the tray. Even assuming that perfect rotational alignment between the sleeve and tray aperture can be achieved, one of ordinary skill in the art certainly would not be motivated to modify the Brodner sleeve in this manner, since it would frustrate the ability to easily place the sleeves within the tray apertures. That is, it would require several manual rotations of the sleeve in order to find the perfect fit between sleeve and tray aperture. It should be noted that in the case where the locking action of the Brodner device is created by pressing the ridges of the sleeve into engagement against the ridges of the tray aperture (as opposed to pressing engagement of the sleeve ridges between the tray ridges), axial alignment between the sleeve and tray aperture is necessary. In this case, rotation of the sleeve will not facilitate placement of the sleeve within the tray aperture.

Appellant does not necessarily disagree that rotation of the sleeve would still be needed if the lowermost surfaces of the ridges were beveled. However, this sleeve rotation would be a natural consequence that would occur as a result of the sliding engagement between the beveled lowermost surfaces of the sleeve ridges and the beveled uppermost surfaces of the tray ridges as the sleeve is being placed into the tray. In the case where the locking action of the Brodner device is created by pressing the ridges of the sleeve into engagement with the ridges of the tray, axial alignment between the sleeve and tray naturally occurs as the beveled edges of the sleeve ridges slide against the beveled edges of the tray ridges, thereby causing the vial to be

centered within the tray aperture. Thus, it is clear that the tapered lowermost edges of the Brodner sleeve facilitate initial introduction of the sleeve into the corresponding tray aperture (i.e., it allows the lowermost edges of the sleeve ridges to pass the uppermost edges of the tray aperture), after which the ridges of the sleeve will be pressed into engagement either between the ridges of the tray aperture or against the ridges of the tray aperture.

Lastly, the Appeal Board stated:

If anything, the teaching that the sleeve outer ridges produce a locking type action with the tray ridges (col. 3, lines 38-40) would have fairly suggested, to one of ordinary skill in the art, making the lower edges of both the sleeve outer ridges and the tray ridges perpendicular to the outer surfaces of, respectively, the sleeve and the tray, to maximize the contact area of the abutting ridges and thereby maximize the locking action. (Appeal Decision, page 6, lines 3-10).

Appellant does not understand, however, how making the lower edges of the sleeve outer ridges and tray ridges perpendicular to the outer surfaces of the respective sleeve and tray would maximize the locking action. It is the longitudinal surfaces of the ridges that provide the locking action—not the lowermost edges of the ridges. Maximizing the contact area of the abutting ridges would only serve to make it more difficult to orient the sleeve, so that the ridges of the sleeve could be slid into engagement between the ridges of the tray aperture.

In conclusion, the Examiner has provided no reason as to why one of ordinary skill in the art would be motivated to modify the lowermost surfaces of the Brodner ridges to be perpendicular to the outer surface of the vial body, and Appellant has provided various reasons as to why proper operation of the Brodner assembly would be

precluded, or at the least would be degraded, if the lowermost surfaces of the ridges were so modified.

For the above reasons, Appellant believes that the Examiner's rejections of claim 1-8, 10, and 12-26 should be overturned.

Respectfully submitted,

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Figure A1

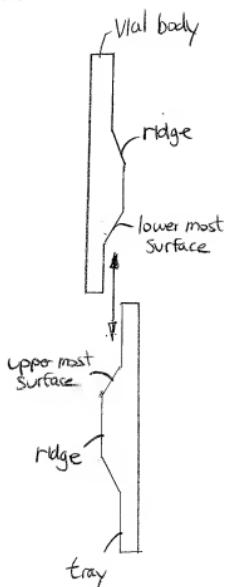


Figure A2

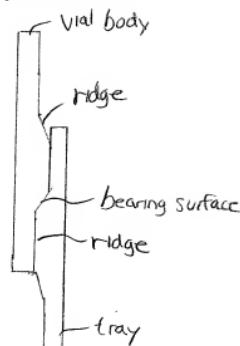


Figure A3

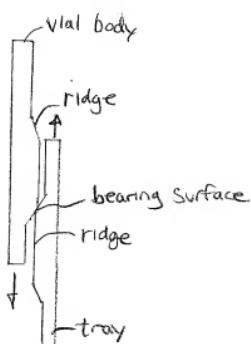


Figure B1

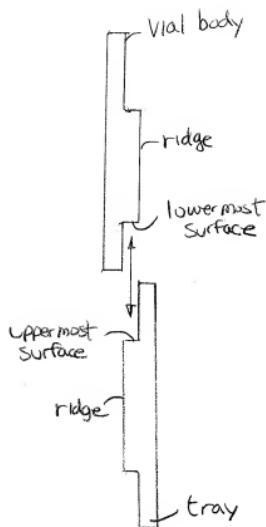


Figure B2

